IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **CASES IDENTIFIED IN EXHIBIT A**	

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF DR. PETER L. ROSENBLATT

Plaintiffs submit this *Memorandum of Law in Support of Plaintiffs' Motion to Limit the Opinions and Testimony of Dr. Peter L. Rosenblatt.* Pursuant to Federal Rules of Evidence 702 and 403 and in support of granting *Plaintiffs' Motion to Limit the Opinions and Testimony of Dr. Peter L. Rosenblatt*, Plaintiffs would show this Honorable Court as follows:

I. SUMMARY OF ARGUMENT

1. Dr. Peter L. Rosenblatt's ("Dr. Rosenblatt") general causation opinions should be limited as follows:

- His opinion that mesh is both safe and effective is unreliable because there is too great an analytical gap between this opinion and the data offered in support. He also testified numerous times that mesh has been effective and successful for "millions of women," but failed to provide any support for this statement. Indeed, it is a conveniently nebulous statement that fails to identify sufficient basis or data, let alone lend itself to being tested consistent with *Daubert*.

- His opinions that the FDA and TV ads regarding mesh have caused "fear mongering" and that women are being taken advantage of do not have a reliable basis as they are purely speculative and/or based on hearsay. They are also unfairly prejudicial to Plaintiffs and as increase the risk of misleading the jury and confusing the issues.

- His opinions regarding the physical properties of mesh are unreliable. The basis for his opinion regarding mesh shrinkage is contradictory to his deposition testimony and there is no evidence that he has ever measured his patients' explants, looked at the pore size of mesh under a microscope, or had a pathologist examine a mesh explant for chronic inflammation or foreign body response.

- His opinions regarding various medical organizations' position statements on mesh are not expert opinions.

II. FACTUAL BACKGROUND

2. Plaintiffs were implanted with mesh devices manufactured, marketed, sold, and designed by Defendants Johnson and & Johnson ("J&J") and Ethicon, Inc. ("Ethicon") (collectively "Defendants").

3. On June 3, 2016, Defendants designated Dr. Rosenblatt as a retained expert witness on general causation.[1] Dr. Rosenblatt further provided a report regarding general Prolene, Gynemesh PS, and Prolift devices.[2]

4. The parties deposed Dr. Rosenblatt on July 1, 2016.[3] However, as described further below, some of Dr. Rosenblatt's opinions and testimony do not meet the requirements for admissibility under the Federal Rules of Evidence.

III. ARGUMENT & AUTHORITIES

A. ADMISSIBILITY OF EXPERT TESTIMONY, GENERALLY

5. The admissibility of expert opinion testimony is governed by the Federal Rules of Evidence.[4] In a federal court sitting in diversity jurisdiction, the admissibility of expert testimony

[1] *See, e.g.,* Plaintiffs' "Exhibit B," attached to Plaintiffs' Motion and incorporated herein.
[2] *See* Plaintiffs' "Exhibit C," attached to Plaintiffs' Motion and incorporated herein.
[3] *See* Plaintiffs' "Exhibit D," attached to Plaintiffs' Motion and incorporated herein.
[4] *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 587 (1993).

is a question of, and controlled by, federal law.[5] In multidistrict litigation, the law of the transferee circuit governs questions of federal law.[6]

6. Federal Rule of Evidence 702 states as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> > (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> >
> > (b) the testimony is based on sufficient facts or data;
> >
> > (c) the testimony is the product of reliable principles and methods; and
> >
> > (d) the expert has reliably applied the principles and methods to the facts of the case.

7. Under *Daubert*, expert evidence is admissible if it "rests on a reliable foundation and is relevant."[7] A court does not have to accept the *ipse dixit* opinion of an expert and "may conclude that there is simply too great an analytical gap between the data and the opinion proffered."[8] The party proffering the expert must present evidence for the court's determination of whether the expert's testimony is admissible.[9]

8. The district court is the gatekeeper to ensure that any and all scientific testimony is both relevant and reliable.[10] As this Court has recognized, "[i]t is an important role" as expert witnesses have the potential to be both powerful and misleading.[11] The Supreme Court established several

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[5] *See, e.g., Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (quoting *Scott v. Sears, Roebuck & Co.*, 789 F.2d 1052, 1054 (4th Cir. 1986)); *Fraley v. Stoddard, D.P.M.*, 73 F. Supp. 2d 642, 646 (S.D. W.Va. 1999).
[6] *See, e.g., In re Temporomandibular Joint Implants Prod. Liab. Litig.*, 97 F.3d 1050, 1155 (8th Cir. 1996) (citation omitted), aff'd, 490 U.S. 122 (1989)); *In re Stucco Litig.*, 364 F. Supp. 2d 539, 540 (E.D.N.C. 2005) ("[i]n the context of this multidistrict case, the court must apply the law of the Fourth Circuit when analyzing questions of federal law."
[7] *Daubert*, 509 U.S. at 597.
[8] *GE v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 519 (1997).
[9] *Md. Cas. Co. v. Therm-O-Disc*, 137 F.3d 780, 783 (4th Cir. 1998).
[10] *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).
[11] *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 516 (S.D. W. Va. 2014) (quoting *Cooper*, 259 F.3d at 199).

factors to guide courts in determining the admissibility of expert testimony: (1) whether the theory or technique "can be (and has been) tested;" (2) "whether the theory has been subjected to peer review or publication;" (3) the "known or potential rate of error;" (4) "the existence and maintenance of standards controlling the technique's operation;" and (5) whether the theory or technique is "generally accept[ed]" in the scientific community.[12]

B. OPINIONS REGARDING THE SAFETY AND EFFICACY OF MESH

9. Dr. Rosenblatt opines in his report that Gynemesh PS and Prolift are both safe and effective.[13] However, in his own practice, Dr. Rosenblatt only occasionally uses Gynemesh PS and does not use the Prolift device:

> Q. Approximately how many of those 300 surgeries that you perform each year involve the use of Ethicon Prolene® mesh?
> MR. ROSENBLATT: Object to form. Jeff, are you referring specifically to Prolene® or are you using Prolene® more broadly? Just --
> MR. CRAWFORD: I want to know Prolene®, how often does he use Ethicon's Prolene® mesh. And my next question will be in how many of those procedures do you use synthetic mesh that's not Ethicon Prolene® mesh?
> MR. ROSENBLATT: Jeff, I'm not trying to be difficult but Gynemesh® PS is also made from Prolene. So I'm just wondering are you asking about Prolene® or Prolene in general.
> Q. Prolene in general.
> A. So it varies per year, but if you want to know currently --
> Q. Yes, sir.
> A. **So I'm still using TVT-O, and <u>occasionally</u> Gynemesh®. I think those are the only two products that I'm currently using**.[14]

[12] *Daubert*, 509 U.S. at 593-94.
[13] *See* Plaintiffs' "Exhibit C" at pp. 32-42.
[14] *See* Plaintiffs' "Exhibit D" at 46:22-47:18 (emphasis added).

Dr. Rosenblatt further testified that last year approximately only 40% of his sling operations involved the use of Ethicon products, and this number has been decreasing the last few years:

> What percentage of your surgeries last year involved Ethicon mesh, those two products that you just referred to?
> A. I would say of the -- I probably do roughly 100 sling operations a year, maybe 100 to 125, and percentage-wise, **probably 40 percent of them are TVT-O**, **but that's been decreasing over the last couple years.** So maybe this year it's probably more like 30 percent or 25 percent.
> Q. **So last year approximately 40 percent of your 100 sling operations involved the use of Ethicon products?**
> A. **I believe that's correct.**
> Q. And that number has decreased this year?
> A. Correct.[15]

The TVT-O device is not at issue in Plaintiffs' cases and Dr. Rosenblatt only "occasionally" uses Gynemesh PS. He does not use the Prolift device. His opinions—especially his clinically-based opinions—are, accordingly, mere conjecture and not based upon a sound methodology or application of sound methodology and should be, respectfully, excluded.

10. Dr. Rosenblatt further opines that "[t]he Gynemesh PS mesh used in Prolift is not defective just because a small percentage of patients might experience mesh exposures or other well-known and acceptable complications."[16] When asked what percentage of Prolift patients would have to experience mesh exposures for him to consider the device defective, Dr. Rosenblatt was unable to give an answer:

> Q. You say in your report that the Gynemesh® PS mesh used in Prolift is not defective just because a small percentage of patients may experience exposures or other well-known and acceptable complications.

[15] *Id*. at 48:1-16 (emphasis added).
[16] *See* Plaintiffs' "Exhibit C" at p. 45.

A. Correct.
Q. In your opinion, what percentage of Prolift patients would have to experience mesh exposures for you to consider the Prolift device defective?
MR. ROSENBLATT: Object to form.
A. So **I don't think there's a specific number**, and different studies show different exposure rates. So I think a lot of it has to do with technique, surgeon technique, as well as, you know, the factors associated with the patient. You know, clinical factors, like age and estrogenization and menopausal status, obesity, comorbidities like diabetes. But, to me, that does not, a specific percentage does not denote a defect in the product itself.
Q. **So there is no particular specific percentage at which you would say this is a defective product?**
MR. ROSENBLATT: Object to form.
Asked and answered.
A. **No**, only in that different studies -- you know, **I've seen exposure rates as high as 20 percent.** I've seen exposure rates of 5 percent or 2 percent. So, you know, every study is different, and you're going to have different exposure rates.[17]

11. There is simply too great an analytical gap between the data and Dr. Rosenblatt's opinion that the Gynemesh PS mesh used in Prolift is not defective. This opinion is unreliable as it is based on studies that allegedly show a small percentage of exposures and other complications, but Dr. Rosenblatt cannot say what percentage would have to exist for him to consider the mesh defective. He further admits that he has seen exposure rates of as high as twenty percent, but fails to explain why he did not take this into consideration in forming his opinion. Dr. Rosenblatt's own testimony shows that his opinions do no rest on a reliable foundation. He clearly ignored studies showing high exposure rates of mesh, without explaining why he did not take these into

[17] *See* Plaintiffs' "Exhibit D" at 60:4-61:10 (emphasis added).

consideration, and further cannot explain what would be a high percentage of exposure and/or complications for the mesh to be considered defective. This opinion is misleading, improper, clearly unreliable and should be, respectfully, excluded.

12. Lastly, Dr. Rosenblatt opines numerous times in his deposition that mesh has been effective and successful for "millions of women:"

> Q. Dr. Rosenzweig has opined that Ethicon's Prolene® mesh is not suitable as a permanent implant for pelvic reconstructive surgery because the pores are too small. Do you agree with that?
> A. No.
> Q. Why not?
> A. **So the Prolene® mesh, you know, has been used in literally, you know, millions of sling cases with phenomenal results**.[18]
>
> …
>
> How does the body respond to a foreign body?
> A. In many different ways, but often it's with fibrosis, but you know, you get fibrosis just with any surgery in the body. You know, think of a scar on your arm if you cut yourself or a keloid, that's scar tissue. So that's a normal response to healing. Another normal response in this case to a foreign body is to try to wall off the foreign body or try to cause scarring or fibrosis around the foreign body, and that is a foreign body response. That doesn't mean it's a bad response. That's a pathologic diagnosis. But we know, and in this case, **we have literally millions of women who've had the surgery, and it's done -- you know, and it's been so beneficial for these women**. So having a foreign body does not mean that it's a bad response of the body to a foreign material.[19]

[18] *See* Plaintiffs' "Exhibit D" at 65:16-25 (emphasis added).
[19] *Id*. at 80:2-21 (emphasis added).

…

Q. If there was credible scientific evidence that polypropylene is cytotoxic, would that render it not suitable for permanent implants in women?
MR. ROSENBLATT: Object to form.
A. No, I think it would have to have some clinical significance.
And again, let's go back and state, as I did earlier, that we've been using polypropylene and Prolene® sutures for decades, and I'm not aware of any untoward effects that that might have of any clinical significance, and you know, you've got -- **you've got several million women that have benefited greatly from this technology over a period of, you know, over 17 years, probably more like 20 years at this point including Europe**, and I think that's sort of a ridiculous statement because we just don't see that clinically.[20]

…

A. So, again, you mentioned mesh, and just so I know which mesh we're talking about –
Q. Prolene®.
A. Prolene® mesh like in TVT?
Q. Yes, sir.
A. I disagree with it because I think it's completely appropriate for use in the vagina, and **that's been borne out after millions of cases.**[21]

13. This nebulous opinion that "millions of women have benefited from mesh" is completely unreliable. Tellingly, Dr. Rosenblatt does not point to any study finding that millions of women have benefitted from mesh and does not suggest that he has personally implanted mesh in millions of women. Moreover, the nebulous reference to undocumented "millions of women" conveniently evades inquiry, and can obviously not be tested. This violation of *Daubert* permits

[20] *Id*. at 87:13-88:6.
[21] *Id*. at 122:24-123:7.

Defendant to tout "millions of women" with successful mesh through the mere *ipse dixit* of its retained expert. There is simply too great an analytical gap between the studies he cites in support of his opinion that mesh is safe and effective and his opinion that millions of women have benefitted from mesh. This opinion is not based on a reliable foundation and it should be, respectfully, excluded.

C. OPINIONS ON "FEAR MONGERING" SURROUNDING MESH AND WOMEN BEING TAKEN ADVANTAGE OF

14. Dr. Rosenblatt is quite critical of the FDA's warnings about mesh complications, as well as the surge in lawsuits regarding mesh complications. He opines in his report that "the FDA should not have made the statement that complications associated with TVM are not rare. In doing so, they opened the door to plaintiff attorneys who have now filed tens of thousands of cases within MDLs, primarily against medical device manufacturers of TVM devices."[22] He further opined as follows in his deposition:

> Q. Do you criticize the FDA for opening the door to plaintiffs attorneys who've now filed tens of thousands of cases against medical device manufacturers for transvaginal mesh?
> A. I think that's part of the situation. I don't think it rests solely with the FDA, but I think that contributed to it.
> Q. What else do you believe contributes to it?
> MR. ROSENBLATT: Object to form.
> A. **I believe the fear mongering with all the plaintiff ads on TV have done a real disservice to women throughout this country.**
> Q. Anything else?
> A. The only thing that comes to mind are, you know, I recall seeing an article in Reuters about medical lenders who are also taking advantage of, I believe, the situation and taking advantage of women who may have problems with

[22] *See* Plaintiffs' "Exhibit C" at p. 15.

> mesh.
> Q. In what ways are they taking advantage?
> A. By lending patients money and jacking up the bills artificially so that when women get their settlements most of the settlement money goes to the entrepreneurs and not to the patients who have been hurt by these, potentially hurt by these procedures.
> Q. What evidence do you have that that's going on?
> A. Just an article that I read in Reuters about this.
> Q. Do you have any personal knowledge regarding that going on?
> A. Yes, my personal knowledge is my discussions with a urogynecologist colleague of mine named Dr. Cassidenti in the Los Angeles area who was contacted by one of these medical lenders and was asked to remove mesh in women and would be paid cash to do this.
> Q. **Any other evidence?**
> A. **Not that I can think of.**
> Q. Have you yourself been approached by any such lenders?
> A. I have not.[23]

Dr. Rosenblatt also opined in his deposition that he is doing more Burch procedures lately "because of all the, again, **fear mongering**, that women come in and have a – **they're afraid of mesh**."[24]

He also testified as follows:

> Q. The reason you're performing more Burch procedures in recent years is due to fear of complications by the general public concerning the use of polypropylene mesh slings, true?
> A. No. **It's because of patient's anxiety seeing ads on TV and what they read in the internet about transvaginal mesh**, and they equate midurethral slings with transvaginal mesh, and some women will come in with an attitude, please do not talk to me about using any mesh in the vagina.

[23] *See* Plaintiffs' "Exhibit D" at 44:2-46:18 (emphasis added).
[24] *Id.* at 88:14-90:9 (emphasis added).

> Q. Does that irritate you when that happens?
> A. I think irritate's the wrong word. I think -- you know, I'm -- **I think it's a shame that women have -- you know, that women are being exposed to this** because first and foremost my goal is to take care of my patients and to offer them the best treatment possible. Although I think a Burch is a good procedure, I don't think it's the best treatment possible, and I think what we're going to be seeing are more patients coming back with recurrences of their stress incontinence, and you know, I hope that's not the case, but I do know it's the case just if you look at the literature. Ultimately there is a decrease in the efficacy of a Burch procedure over time.[25]

15. "A reliable expert opinion must be based on scientific, technical, or other specialized *knowledge* ***and not on belief or speculation***, and inferences must be derived using scientific or other valid methods."[26] The above "opinions" are based on mere speculation and belief, and clearly do not rest on a reliable foundation. Dr. Rosenblatt does not offer any evidence that the FDA "opened the door" to thousands of lawsuits or that TV ads have caused "fear mongering" regarding mesh implants. Furthermore, the only evidence he offers in support of his claim that "women are being taken advantage of" is a Reuters article, which he does not identify, and a hearsay statement allegedly made by his colleague. These "opinions," once again, are speculative comments immune from any analysis or testing by the undersigned and their experts. Accordingly, these inflammatory comments, which are more attuned to a closing argument, are merely *ipse dixit*—entirely based on his own belief and speculation. Respectfully, they should be excluded.

16. These opinions are also unfairly prejudicial to Plaintiffs, as well as confusing and misleading. A court may also exclude relevant evidence "if its probative value is substantially

[25] *Id*. at 91:8-92:10 (emphasis added).
[26] *Oglesby v. GMC*, 190 F.3d 244, 250 (4th Cir. 1999) (emphasis added).

outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."[27] This Court has noted that this Rule has "particular significance in *Daubert* decisions because 'expert evidence can be both powerful and misleading.'"[28]

17. The danger of unfair prejudice to Plaintiffs or misleading the jury substantially outweighs the probative value of these opinions. The jury could imply from these opinions that Plaintiffs only filed suit 1) based on "fear mongering" or 2) that they have been taken advantage of, or 3) will be taken advantage of at the conclusion of the suit. Furthermore, there is a risk of confusing the issues as these opinions clearly take the focus away for the ultimate questions of liability in these cases.

D. OPINIONS ON THE PHYSICAL PROPERTIES OF MESH

18. Dr. Rosenblatt offers several unreliable opinions on the physical properties of mesh. First, he does not believe that there is shrinkage of polypropylene mesh and states as follows in his report: "[p]olypropylene fibers and mesh do not have contractile elements; **there is no scientific evidence that the fibers or the mesh itself undergoes any shrinkage of any kind**."[29] However, despite making this unequivocal statement regarding mesh shrinkage, he acknowledged in his deposition that there are studies by Ethicon's consultants acknowledging that mesh shrinks and further stated that whether mesh shrinks is "debatable and controversial:"

> Q. Since you are of the opinion that mesh does not shrink, **am I safe to assume you dispute that shrinkage was known by Ethicon as early as 1998 in published works by Ethicon's many consultants, Uwe Klinge and Bernd Klosterhalfen?**

[27] FED. R. EVID. 403.
[28] *Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 U.S. Dist. LEXIS 137189, at *95-96 (S.D. W. Va. 2014) (quoting *Daubert*, 509 U.S. at 595).
[29] *See* Plaintiffs' "Exhibit C" at p. 22 (emphasis added).

A. **So I am aware of that, and I have seen those reports**, but the first part of your statement was that I don't believe that mesh shrinks, and mesh does not shrink. There's no such thing as mesh shrinking. It's not like you put it in a dryer like, you know, a shirt in a dryer and it gets smaller. It's the fibrosis that occurs as a natural healing process of surgery that causes shrinkage. Because as I said, native tissue repairs you can get stenosis of the vagina, you can get foreshortening of the vagina. Mesh does not shrink. So if there is any decrease in the surface area of the mesh, it's not from the mesh itself. It's the tissue around the mesh.

MR. CRAWFORD: Object and move to strike the non-responsive portions of that answer.

You are familiar with the Klinge and the Klosterhalfen study.

A. Yes.

Q. And you're aware that they noted in their paper that polypropylene mesh shrinks 30 to 50 percent; is that right?

MR. ROSENBLATT: Object to form.

If you have the paper and you want to put it in front of him, he can take a look at it.

A. Yeah, I was about to say I'd like to see the paper 'cause I want to see if that was from an animal study. **I am familiar with the so-called, you know, quote/unquote, shrinkage or contracture in hernia meshes**, but I'm almost familiar with literature -- the one that comes to mind is Dietz -- I think it's D-E-I-T-Z or D-I-E-T-Z -- that shows using ultrasound that there is no shrinkage of mesh implanted in humans. **So I think that is debatable and controversial.**

Q. Do you agree that if there is credible scientific evidence that polypropylene mesh shrinks 30 to 50 percent and as a result there's an adverse clinical effect on the patient, then it's not suitable for its intended application as a permanent prosthetic implant in women?

MR. ROSENBLATT: Object to form.

> Lack of foundation, compound.
> A. What you're suggesting is not the case. You know, and the reason I say that and I'm comfortable saying that is **I've been implanting mesh transvaginally for 15 years, and I do not see that clinically.**
> Could a particular woman have a fibrotic reaction where she would have had a fibrotic reaction and scarring with a native tissue repair? Yeah, that can happen, and there might be mesh there, but I do not see that -- when you say, you know, if you could show that mesh -- mesh does not shrink. **So it doesn't make a lot of sense to me to assume that, you know, mesh shrinks 'cause it doesn't shrink**.[30]

19. Dr. Rosenblatt's report and deposition testimony regarding the basis for his opinion that mesh does not shrink are contradictory. His report clearly and unequivocally states that "**there is no scientific evidence that the fibers or the mesh itself undergoes any shrinkage of any kind,**" yet he admits in his deposition that he is aware of studies showing that mesh shrinks and that the topic of mesh shrinkage is "debatable and controversial." His opinion is further unreliable as he bases his opinion on a "fact" which is simply not true and does not explain why he finds the other literature showing that mesh shrinks unpersuasive. Furthermore, to the extent he bases his opinion on his general experience, his opinion is still unreliable as there is no evidence that he ever measured the mesh or did anything else to verify that mesh does not shrink, besides his general observation.[31] How could Dr. Rosenblatt's nebulous, unspecified clinical experience with mesh (much of which is not even relevant products) ever be tested consistent with *Daubert*? It can not, which is precisely the purpose of its cryptic design.

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[30] *See* Plaintiffs' "Exhibit D" at 116:20-119:11 (emphasis added).

[31] *See Winebarger v. Bos. Sci. Corp.*, No. 2:13-cv-28892, 2015 U.S. Dist. LEXIS 53892, at *101-03 (S.D. W. Va. 2015); *Carlson v. Bos. Sci. Corp.*, No. 2:13-cv-05475, 2015 U.S. Dist. LEXIS 55282, at *104-06 (S.D. W. Va. 2015) (excluding opinions regarding mesh shrinkage as unreliable where the expert had never measured patients' explants for shrinkage, even though he relied heavily on his clinical experience and had considered scientific literature in forming his opinions).

20. Second, Dr. Rosenblatt opines that "Type 1 polypropylene mesh is macroporous, which allows the integration of the host's tissue into the mesh. **This is apparent clinically** whenever we need to make adjustments to mesh."[32] He further states that "the pore size allows macrophages to enter within the structure of the mesh during the healing phase so that any bacteria can be dealt with, preventing infection of the mesh."[33] These opinions regarding pore size are unreliable, however, because Dr. Rosenblatt generally states that pore size is "apparent clinically" and there is no evidence that Dr. Rosenblatt has ever measured pore size under a microscope.[34]

21. Lastly, Dr. Rosenblatt opines that he has not seen any degradation of polypropylene mesh and has not found any reliable scientific literature showing that mesh degrades.[35] He also testified in his deposition that he does not agree that mesh is unsuitable for permanent implantation because it causes chronic foreign body reactions.[36] These opinions are unreliable, however, because there is no evidence that he has ever asked pathologists to examine his explants for chronic inflammation or foreign body response.[37]

22. Dr. Rosenblatt's opinions on the physical properties of mesh are clearly unreliable and should be excluded accordingly.

E. OPINIONS ON POSITION STATEMENTS

[32] *See* Plaintiffs' "Exhibit C" at p. 22 (emphasis added).
[33] *Id*. at 22-23.
[34] *See Winebarger*, 2015 U.S. Dist. LEXIS 53892, at *101-03; *Carlson*, 2015 U.S. Dist. LEXIS 55282, at *104-06 (excluding opinions regarding pore size as unreliable where the expert had never measured under a microscope the pore size of any device, even though he relied heavily on his clinical experience and had considered scientific literature in forming his opinions).
[35] *See* Plaintiffs' "Exhibit C" at p. 21-22.
[36] *See* Plaintiffs' "Exhibit D" at 72:13-73:7.
[37] *See Winebarger*, 2015 U.S. Dist. LEXIS 53892, at *101-03; *Carlson*, 2015 U.S. Dist. LEXIS 55282, at *104-06 (excluding opinions regarding degradation and foreign body response as unreliable where the expert had never asked a pathologist to examine his explants for chronic inflammation or foreign body response, even though he relied heavily on his clinical experience and had considered scientific literature in forming his opinions).

23. Dr. Rosenblatt's Report discusses in great detail the various position statements issued by various medical organizations, including AUGS, on TVM.[38] This Court has repeatedly held that "position statements are not expert opinions."[39] These opinions should, accordingly, be excluded in their entirety.

IV. CONCLUSION

24. Plaintiffs respectfully request that the Court exclude the above opinions offered by Dr. Rosenblatt because they do not meet the standards set out under Rule 702 or in *Daubert*. These opinions are further unfairly prejudicial to Plaintiffs under Rule 403 and also have the potential to mislead the jury or confuse the issues in these cases.

Respectfully submitted,

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[38] *See* Plaintiffs' "Exhibit C" at p. 27-32.
[39] *Tyree*, 54 F. Supp. 3d at 574; *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 720 (S.D. W. Va. 2014);

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing has been forwarded to all counsel of record on this 21st day of July, 2016, in accordance with the Federal Rules of Civil Procedure.

/s/ Mark Sparks
Mark Sparks